IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

UNITED STATES OF AMERICA,

Plaintiff,

v.

LAWSON FARM, and
ROBERT LAWSON,
GEORGE R. LAWSON, and
LONNIE A. GRIFFIN,
individuals,

Defendants.

CIVIL ACTION NO. 1:13-CV-179

COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, alleges as follows:

INTRODUCTION

1. This action is brought by the United States of America pursuant to the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to enjoin and restrain Defendants from violating:

a. 21 U.S.C. § 331(a), by introducing and causing to be introduced into interstate commerce, and delivering and causing to be delivered for introduction into interstate commerce, food that is adulterated within the meaning of 21 U.S.C. §§ 342(a)(2)(C)(ii) and 342(a)(4);

b. 21 U.S.C. § 331(k), by causing drugs to become adulterated within the meaning of 21 U.S.C. § 351(a)(5), while such drugs are held for sale after shipment in interstate commerce; and

c. 21 U.S.C. § 331(u), by failing to comply with the conditions for new animal drug use within the meaning of 21 U.S.C. § 360b(a)(4)(A).

JURISDICTION AND VENUE

2. This Court has jurisdiction pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331 and 1345.

3. Venue in this District is proper pursuant to 28 U.S.C. § 1391(b).

DEFENDANTS

4. Defendant Lawson Farm is a sole proprietorship located at 581 Airport Road, Irasburg, Vermont, within the jurisdiction of this Court. Lawson Farm operates a dairy farm and regularly sells bull calves and dairy cows for slaughter for use as human food.

5. Defendant Robert Lawson and his wife, Janet Lawson, have owned Lawson Farm since approximately 1979. Robert Lawson has received numerous warnings from the U.S. Food and Drug Administration ("FDA") and U.S. Department of Agriculture ("USDA") regarding the violations alleged in this complaint.

6. Defendant George R. Lawson, son of Defendant Robert Lawson, is the most responsible person at Lawson Farm. George Lawson has been the farm's manager for over twenty years and is responsible for overseeing the farm's dairy operations, including supervising the herdsmen and overseeing the administration of drugs to cattle and introduction into interstate commerce of cattle for use as human food.

7. Defendant Lonnie A. Griffin has been the farm's herdsman for approximately eleven years. He supervises seven employees and is responsible for deciding when to administer drugs to animals, monitoring drug withdrawal times, and maintaining treatment records. When Defendant George Lawson is absent, Defendant Griffin is the most responsible person at the farm.

8. Defendants deliver and cause the delivery of food, as defined in 21 U.S.C. § 321(f), for introduction into interstate commerce. Specifically, Defendants sell cattle that are routinely delivered for slaughter for use as human food to locations outside of Vermont, including Wyalusing, Pennsylvania and Vernon, New York.

9. Defendants medicate their animals with drugs that have been shipped in interstate commerce.

STATUTORY AND REGULATORY PROVISIONS

10. The drugs that Defendants use to treat their cows, including, but not limited to, penicillin, flunixin, sulfamethazine, neomycin, tilmicosin, and oxytetracycline, are new animal drugs within the meaning of 21 U.S.C. § 321(v).

11. FDA approves new animal drugs that are shown to be safe and effective for use under specified conditions. 21 U.S.C. § 360b(d)(1).

12. A new animal drug's conditions for use are set forth in the drug's approved labeling and are published by regulation. 21 C.F.R. § 514.105(a). The conditions for use include the legal purposes for which the drug may be used (indications), the amount of the drug that may be administered to an animal (dosage), the types of animals to which the drug may be administered (species limitations), the maximum amount of the drug or its residue that may be contained in the tissue of animals delivered for slaughter for use as food (tolerance), and the pre-slaughter withdrawal period required to prevent above-tolerance concentrations of the drug from remaining in the edible tissues of treated animals (withdrawal period). 21 U.S.C. § 360b(i); 21 C.F.R. Parts 520–29, 556.

13. A new animal drug is unsafe as a matter of law when there is no FDA approval in effect for its use or where the actual use of the drug does not conform to the conditions of the drug's approval. A licensed veterinarian, in the context of a valid veterinarian-client-patient relationship ("VCPR"), may prescribe a use of a new animal drug that differs from that specified in the drug's labeling (an "extralabel" use), provided that such use does not result in an illegal drug residue in edible animal tissues and that such drug is not prohibited from extralabel use under 21 C.F.R. Part 530. 21 U.S.C. §§ 360b(a)(1), 360b(a)(4)(A), (B).

14. The administration of a new animal drug in a manner contrary to the conditions for use approved by FDA that results in any residue above the established tolerance renders the drug unsafe within the meaning of 21 U.S.C. § 360b(a)(1). *See* 21 C.F.R. § 530.11(d).

15. A new animal drug that is unsafe within the meaning of 21 U.S.C. § 360b is deemed to be adulterated. 21 U.S.C. § 351(a)(5).

16. Animals intended for slaughter for use as human food are food within the meaning of the Act. 21 U.S.C. § 321(f).

17. Food containing an unsafe new animal drug is deemed to be adulterated. 21 U.S.C. § 342(a)(2)(C)(ii).

18. The edible tissues of animals treated with new animal drugs are adulterated within the meaning of 21 U.S.C. § 342(a)(4) if they are held under insanitary conditions in which they may be rendered injurious to health.

19. FDA has approved flunixin, neomycin, penicillin, oxytetracycline, sulfamethazine, and tilmicosin under specified conditions, *see* 21 C.F.R. §§ 520.970, 522.970, 520.1484, 522.1484, 520.1696, 522.1696, 520.1660, 522.1660, 520.2260, 522.2260, 522.2471, and has set

tolerances for these drugs in animals, *see* 21 C.F.R. §§ 556.286, 556.430, 556.510, 556.500, 556.670, 556.735.

20. Tilmicosin is not approved for use in dairy cows 20 months or older. 21 C.F.R. § 522.2471(e)(iii). For other cattle, the tolerance for the drug in muscle is 0.1 ppm. *See* 21 C.F.R. § 556.735(b)(ii).

21. Sulfamethazine's tolerance in the uncooked edible tissues of cattle is 0.1 ppm. 21 C.F.R. § 556.670. Extralabel sulfamethazine use in lactating dairy cattle is prohibited. 21 C.F.R. § 530.41(a)(9).

22. In 2003, flunixin was not approved for use in lactating dairy cattle. Flunixin was approved for use in such cattle in October 2004, and the drug's tolerance in liver was set at 0.125 ppm. 21 C.F.R. §§ 522.970, 556.286.

PUBLIC HEALTH RISKS

23. Levels of new animal drugs in an animal's edible tissues above the amounts permitted by law and regulation pose significant public health risks. Consumers sensitive to certain drugs may experience severe allergic reactions, such as life-threatening anaphylaxis (shock), angioneurotic edema (severe swelling of the skin), and/or serum sickness (fever, skin rash, and pain in the joints), if they consume animal tissue containing above-tolerance drug levels. Food containing above-tolerance residues of antibiotics contributes to the development of antibiotic-resistant strains of bacteria in humans who eat or handle such food. In addition, certain above-tolerance animal drug residues can be toxic to human organs, especially the kidneys, liver, ears, gastrointestinal system, and heart. For instance, violative residues of tilmicosin can be toxic to the heart, and chronic exposure to such residues can lead to increased mortality.

FDA INSPECTIONS

USDA Laboratory Testing

24. USDA collected tissue samples from dairy cows that Defendants introduced into interstate commerce for slaughter for use as human food and analyzed those samples for drug residues.

25. Between 2002 and 2012, USDA's testing identified illegal residues of six new animal drugs (penicillin, neomycin, tilmicosin, sulfamethazine, flunixin, and oxytetracycline) in tissue samples collected from ten of Defendants' animals. The results of these tests are as follows:

	Sample Collection Date	USDA Lab Report Number	Species	Animal Tag Number	Tissue	Drug Residue	Residue Amount (ppm)	Tolerance (ppm)
a.	11/21/12	100319920	Cow	1110	Kidney	Penicillin	0.782	0.05
b.	8/24/11	504319	Cow	48	Kidney	Penicillin	0.16	0.05
c.	5/18/10	497532	Bob Veal	5121	Kidney	Neomycin	12.95	7.2
d.	5/25/07	503986	Cow	5659	Muscle	Tilmicosin	3.669	See ¶ 20
e.	5/22/07	503978	Cow	7162	Liver	Sulfamethazine	4.12	See ¶ 21
					Muscle	Sulfamethazine	1.68	See ¶ 21
f.	1/31/07	503684	Cow	4403	Kidney	Penicillin	0.09	0.05
g.	6/8/05	460468	Cow	6070	Liver	Penicillin	0.14	0.05
h.	5/10/05	460359	Cow	5860	Kidney	Penicillin	0.10	0.05
					Liver	Penicillin	0.19	0.05
i.	9/5/03	433288	Cow	3553	Liver	Flunixin	0.131	See ¶ 22
j.	10/18/02	446125	Cow	207761	Liver	Oxytetracycline	19.21	6
					Muscle	Oxytetracycline	5.78	2
					Kidney	Oxytetracycline	40.95	12
					Liver	Sulfamethazine	2.07	0.1
					Muscle	Sulfamethazine	1.24	0.1

2012 Inspections

26. FDA most recently inspected Defendant Lawson Farm between May 31 and June 25, 2012, and again on July 25, 2012, and August 1, 2012, after USDA detected illegal drug residues in bob veal 5121 and cow 48, which Defendants had sold for slaughter for use as human food.

The FDA investigator observed and documented the following violative conditions during these inspections:

a. Defendants caused illegal residues in food-producing animals of approved new animal drugs by using the drugs contrary to their labeling and failing to take appropriate measures to assure that assigned time frames for withdrawal were met and that no illegal residue occurred;

b. Defendants administered new animal drugs penicillin, flunixin, and neomycin in an extralabel manner without a veterinarian's prescription in the context of a valid VCPR;

c. Defendants did not maintain adequate treatment records. Specifically, Defendants did not document route of administration or the name of the individual administering a treatment in their records; and

d. Defendants keep expired drugs in their drug storage area.

27. According to Lawson Farm's treatment records reviewed by the FDA investigator, Defendants administered 40 cc of penicillin to cow 48 on August 14, 2011, 10 days before it was slaughtered for use as human food. At the time of this administration, penicillin's approved label specified a dosage of 10 cc per injection site and one cc per 100 lbs of body weight, with a 14-day withdrawal period.

28. The FDA investigator found that Defendants used new animal drugs in an extralabel manner without the benefit of a valid veterinarian's prescription in the context of a valid VCPR. Defendants administered 20 cc of flunixin intravenously to cow 48 on August 14, 2011, and used flunixin to treat high temperature and pain. At the time of administration, flunixin's label specified a dose of one cc per 100 lbs of body weight to treat endotoxic shock. The FDA

investigator determined that the farm's veterinarian did not prescribe Defendants' extralabel use of penicillin or flunixin in cow 48.

29. The FDA investigator found that Defendants failed to document the route of administration and the name of the person administering the drug in their records.

30. The FDA investigator found expired new animal drugs in Defendants' drug storage area.

31. FDA investigators issued Forms FDA 483, List of Inspectional Observations ("Forms 483"), documenting the observations listed in paragraphs 26–30 to Defendant George Lawson on June 25, 2012, and to Defendant Robert Lawson on August 1, 2012.

2007 Inspection

32. FDA inspected Defendants on October 24 and 25, 2007, after USDA identified four illegal drug residues in three cows (4403, 7162, and 5659) that Defendants had sold for slaughter for use as human food. The FDA investigators observed and documented the following violative conditions:

a. Defendants caused illegal residues in food-producing animals of approved animal drugs by using the drugs contrary to their labeling and failing to take appropriate measures to assure that assigned time frames for withdrawal were met and that no illegal residue occurred;

b. Defendants administered new animal drugs penicillin, sulfamethazine, and tilmicosin in an extralabel manner without a valid veterinarian's prescription in the context of a valid VCPR;

c. Defendants did not maintain adequate treatment records. Specifically, Defendants did not record the administration of penicillin, sulfamethazine, or tilmicosin to cows 4403, 7162, and 5659, and Defendants did not document route of administration, withdrawal times, or the name of the person administering treatment in any of their records; and

d. Defendants keep expired drugs in their drug storage area.

33. Defendants sold cow 4403 for slaughter after treating it with penicillin, in violation of the drug's 10-day withdrawal period.

34. Defendants administered sulfamethazine sodium 12.5% to their cows by intravenous injection at a dose of 500 ml once per day for two days. At that time, the drug's approved label specified administration via drinking water and a dosage of 3 fl oz (approximately 89 ml) per 100 lbs of body weight on the first day of treatment and 1.5 fl oz (approximately 44 ml) per 100 lbs of body weight on days two through four.

35. FDA investigators found that Defendants administered tilmicosin to their cows at a dose of 1 cc per 100 pounds of body weight via intramuscular injection. Tilmicosin's approved label specified a dose of 1.5 cc per 100 pounds of body weight via subcutaneous injection.

36. FDA investigators determined that Lawson Farm's veterinarian did not prescribe Defendants' extralabel use of penicillin, sulfamethazine sodium 12.5%, or tilmicosin.

37. FDA investigators found that Defendants did not record the administration of penicillin, sulfamethazine, or tilmicosin to, respectively, cows 4403, 7162, and 5659, and Defendants did not document route of administration, withdrawal times, or the name of the person administering treatment in any of their records.

38. FDA investigators found that Defendants kept an expired drug in their drug storage area.

39. FDA investigators issued to Defendant George Lawson a Form 483 documenting the observations listed in paragraphs 32–38.

2005 Inspection

40. FDA inspected Defendants in October and November 2005, after USDA identified three illegal penicillin residues in two cows (5860 and 6070) that Defendants had sold for slaughter for use as human food. FDA investigators observed and documented the following violative conditions:

a. Defendants caused illegal residues in food-producing animals of approved animal drugs by using the drugs contrary to their labeling and failing to take appropriate measures to assure that assigned time frames for withdrawal were met and that no illegal residue occurred;

b. Defendants did not maintain adequate treatment records. Specifically, Defendants did not record the administration of penicillin in cow 6070; and

c. Defendants lack an inventory system for determining the quantities of drugs used to medicate their cattle.

41. Lawson Farm's treatment records showed that Defendants administered penicillin to cow 5860 at a dose of 60 cc, on or before May 4, 2005, which was six days before Defendants sold the cow for slaughter. At the time of administration, penicillin's approved label specified a maximum dose of 10 cc per site and a withdrawal period of 10 days.

42. FDA investigators issued to Defendant George Lawson a Form 483, documenting the observations listed in paragraphs 40–41.

DEFENDANTS' CONDUCT AND VIOLATIONS

Defendants Violate 21 U.S.C. § 331(a)

43. Administration of a new animal drug in a manner contrary to the conditions for use approved by FDA that results in an illegal residue causes the drug to be unsafe within the meaning of 21 U.S.C. § 360b(a)(1).

44. Because the edible tissues of animals Defendants sold for slaughter for use as human food contained new animal drugs that were unsafe within the meaning of 21 U.S.C. § 360b(a)(1), the animals and their edible tissues were adulterated within the meaning of 21 U.S.C. § 342(a)(2)(C)(ii).

45. Defendants' improper drug administration practices and poor record-keeping practices constitute insanitary conditions whereby the edible tissues of their animals may have been rendered injurious to health which, in turn, caused these animals and their edible tissues to be adulterated within the meaning of 21 U.S.C. § 342(a)(4).

46. Defendants' violative practices have resulted in the introduction into interstate commerce of at least seven dairy cows that contained illegal residues in their edible tissues.

47. Defendants violate 21 U.S.C. § 331(a) by introducing and delivering for introduction into interstate commerce food that is adulterated within the meaning of 21 U.S.C. §§ 342(a)(2)(C)(ii), 342(a)(4).

Defendants Violate 21 U.S.C. § 331(k)

48. Defendants receive new animal drugs (e.g., penicillin, flunixin, and sulfamethazine) in interstate commerce.

49. Defendants hold these drugs for sale after they have been shipped in interstate commerce within the meaning of 21 U.S.C. § 331(k).

50. Because Defendants use new animal drugs in ways that are inconsistent with the drugs' approved conditions for use and extralabel use exemptions, these drugs are unsafe within the meaning of 21 U.S.C. § 360b(a)(1), which, in turn, caused the drugs to be adulterated within the meaning of 21 U.S.C. § 351(a)(5).

51. Defendants violate 21 U.S.C. § 331(k) by causing new animal drugs to become adulterated within the meaning of 21 U.S.C. § 351(a)(5) while such drugs are held for sale after shipment in interstate commerce.

Defendants Violate 21 U.S.C. § 331(u)

52. Because Defendants use new animal drugs in ways that are inconsistent with the drugs' approved conditions for use and extralabel use exemptions, Defendants' use of these drugs does not comply with the conditions for use within the meaning of 21 U.S.C. § 360b(a)(4)(A).

53. Defendants violate 21 U.S.C. § 331(u) by failing to comply with the conditions for new animal drug use within the meaning of 21 U.S.C. § 360b(a)(4)(A).

HISTORY

54. FDA and USDA have repeatedly warned Defendants of their continued violations of the Act.

55. FDA investigators provided Defendants with Forms 483 after each inspection, documenting Defendants' violations of the Act.

56. FDA issued a Warning Letter to Defendant Robert Lawson on December 21, 2005, advising Defendant that he offered for sale for slaughter as human food animals with illegal drug residues in violation of the Act, 21 U.S.C. § 342(a)(2)(C)(ii) and 342(a)(4), and caused a new animal drug to become adulterated within the meaning of the Act, 21 U.S.C. § 351(a)(5). The Warning Letter notified him that failure to correct such violations could result in regulatory action, such as seizure and/or injunction, without further notice.

57. On January 2, 2008, FDA held a regulatory meeting with Defendant George Lawson, during which FDA warned him that future violations of the Act could cause FDA to seek further action, including injunction.

58. Between 2005 and 2013, USDA sent eight letters to Defendants Robert Lawson and Lawson Farm stating that USDA detected violative residues in cattle offered for slaughter by Defendants. The letters warned that violative drug residues in the edible tissues of animals cause the food to be adulterated under the Act. Most recently, a letter dated January 15, 2013, informed Defendants of a penicillin residue detected on November 21, 2012, in the edible tissues of a cow originating from Lawson Farm.

59. Despite FDA and USDA's multiple warnings, Defendants continue to violate the Act. Based on Defendants' repeated violations, Plaintiff is informed and believes that, unless restrained by order of the Court, Defendants will continue to violate 21 U.S.C. §§ 331(a), (k), and (u).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

I. Permanently restrain and enjoin, under the provisions of 21 U.S.C. § 332(a), Defendants and each of their agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates) who receive actual notice of the Court's order from, directly or indirectly:

A. violating 21 U.S.C. § 331(a) by introducing, delivering, and causing the introduction and delivery for introduction into interstate commerce, any article of food that is adulterated within the meaning of 21 U.S.C. §§ 342(a)(2)(C)(ii) or 342(a)(4);

B. violating 21 U.S.C. § 331(k) by doing or causing to be done any act that causes an article of drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(5), while such drug is held for sale after its shipment in interstate commerce; and/or

C. violating 21 U.S.C. § 331(u) by failing to comply with the conditions for new animal drug use within the meaning of 21 U.S.C. § 360b(a)(4)(A);

II. Order Defendants and each and all of their agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates) who receive actual notice of the Court's order, unless and until Defendants bring their operations into compliance with the law to the satisfaction of FDA, to do the following:

A. cease introducing, delivering, and causing to be introduced and delivered into interstate commerce any article of food, within the meaning of 21 U.S.C. § 321(f), consisting of animals and their edible tissues; and

B. cease administering to animals any new animal drug, within the meaning of 21 U.S.C. § 321(v), while such drug is held for sale after shipment in interstate commerce, except that Defendants may administer a new animal drug to an animal that has been examined and diagnosed with an illness by a licensed veterinarian who prescribes the specific drug for that animal and Defendants maintain all records of the animal's diagnosis and treatment;

III. Authorize FDA, pursuant to this injunction, to inspect Defendants' place of business to ensure continuing compliance with the terms of this injunction, with the costs of such inspections to be born by Defendants at the rates prevailing at the time the inspections are performed; and

IV. Award the Plaintiff its costs herein, including costs of investigation to date, and such other relief as the Court may deem just and proper.

Dated this 20th day of June, 2013.

Respectfully submitted,

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